



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/771,951	02/03/2004	Dong-Er Zhang	AP35942 - 074779.0106	3767

21003 7590 01/11/2005

BAKER & BOTTS
30 ROCKEFELLER PLAZA
NEW YORK, NY 10112

EXAMINER

HAMA, JOANNE

ART UNIT PAPER NUMBER

1632

DATE MAILED: 01/11/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/771,951	Applicant(s) ZHANG ET AL.	
	Examiner Joanne Hama, Ph.D.	Art Unit 1632	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 03 February 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-54 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-54 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

Art Unit: 1632

This Application, filed February 3, 2004, claims priority to U.S. Provisional Application 60/444,941, filed February 3, 2003.

Claims 1-54 are under consideration.

Restriction to one of the following inventions is required under 35 U.S.C.

121:

- I. Claims 1-12, drawn to a method to identify an agent that alters UBP43 activity, classified in class 424, subclass 9.1.
- II. Claims 13-18, 47, drawn to a method to induce a cell to undergo apoptosis, classified in class 435, subclass 325, or in class 530, subclass 350+.
- III. Claims 19-23, 48, drawn to a method to prolong or increase the response of a cell to interferon, classified in class 435, subclass 325, or in class 530, subclass 350+.
- IV. Claims 24-28, drawn to a method to inhibit cell proliferation, classified in class 435, subclass 325, or in class 530, subclass 350+.
- V. Claims 29-31, 49, drawn to a method to inhibit the infection or replication of a virus, classified in class 435, subclass 325, or in class 530, subclass 350+.
- VI. Claims 32-34, drawn to a method to treat an autoimmune disease, classified in class 514, subclass 44.

Art Unit: 1632

- VII. Claims 35-37, 51, drawn to a method to increase the effectiveness of an anticancer therapeutic, classified in class 514, subclass 44.
- VIII. Claims 38-43, drawn to an ISG15-conjugate and a composition comprising an ISG15-conjugate, classified in class 530, subclass 350+.
- IX. Claims 44,52, drawn to a method to increase phagocytic activity of a cell, classified in class 435, subclass 325, or in class 530, subclass 350+.
- X. Claim 45, 53, drawn to a method to increase cell motility, classified in class 435, subclass 325, or in class 530, subclass 350+.
- XI. Claim 46, 54 drawn to a method to enhance wound healing, classified in class 514, subclass 44.

The inventions are distinct, each from the other because of the following reasons:

Inventions II, III, IV, IX and X are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, while each Invention is to a method performed on a cell, each method is different as each method causes a cell to undergo a different biological process. None of these methods depend on the others to function.

Inventions VI, VII, and XI are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have

Art Unit: 1632

different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, while each Invention is to a method performed on an organism, each method is to a different disease or to an enhancement of wound healing. None of these methods depends on the others to function.

Inventions I and II/III/IV/IX/X are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case Invention I is to a method to identify an agent that alters UPB43 activity. Invention II/III/IV/IX/X are to methods performed on a cell, wherein each method is different as each method causes a cell to undergo a different biological process. Inventions I and II/III/IV/IX/X do not depend on each other to function and vice versa.

Inventions I and V are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case Invention I is to a method to identify an agent that alters UPB43 activity. Invention V is to a method to inhibit the infection or replication of a virus. Invention I does not depend on Invention V to function and vice versa.

Inventions I and VI/VII/XI are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have

Art Unit: 1632

different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case Invention I is to a method to identify an agent that alters UPB43 activity. Inventions VI/VII/XI are to methods performed on an organism, wherein each method is to a different disease or to an enhancement of wound healing. Inventions I and VI/VII/XI do not depend on each other to function and vice versa.

Inventions I and VIII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case Invention I is to a method to identify an agent that alters UPB43 activity. Invention VIII is to an ISG15-conjugate and a composition comprising an ISG15-conjugate. Invention I does not depend on Invention VIII to function and vice versa.

Inventions II/III/IV/IX/X and V are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, Invention II/III/IV/IX/X are to methods performed on a cell, wherein each method is different as each method causes a cell to undergo a different biological process. Invention V is to a method to inhibit the infection or replication of a virus. Invention II/III/IV/IX/X do not depend on Invention V to function and vice versa.

Inventions II/III/IV/IX/X and VI/VII/XI are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use

Art Unit: 1632

together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, Invention II/III/IV/IX/X are to methods performed on a cell, wherein each method is different as each method causes a cell to undergo a different biological process.

Inventions VI/VII/XI are to methods performed on an organism, wherein each method is to a different disease or to an enhancement of wound healing.

Inventions II/III/IV/IX/X do not depend on Inventions VI/VII/XI to function and vice versa.

Inventions II/III/IV/IX/X and VIII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, Inventions II/III/IV/IX/X are to methods performed on a cell, wherein each method is different as each method causes a cell to undergo a different biological process. Invention VIII is to an ISG15-conjugate and a composition comprising an ISG15-conjugate. Invention VIII can be used in other methods, such as in the treatment of diseases or in enhancing wound healing.

Inventions V and VI/VII/XI are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, Invention V is to a method to inhibit the infection or replication of a virus. Inventions VI/VII/XI are to methods

Art Unit: 1632

performed on an organism, wherein each method is to a different disease or to an enhancement of wound healing. Invention V does not depend on Inventions VI/VII/XI to function and vice versa.

Inventions V and VIII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, Invention V is to a method to inhibit the infection or replication of a virus. Invention VIII is to an ISG15-conjugate and a composition comprising an ISG15-conjugate. Invention VIII can be used in other methods, such as in the treatment of diseases or in enhancing wound healing.

Inventions VI/VII/XI and VIII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, Inventions VI/VII/XI are to methods performed on an organism, wherein each method is to a different disease or to an enhancement of wound healing. Invention VIII is to an ISG15-conjugate and a composition comprising an ISG15-conjugate. Invention VIII can be used in other methods, such as to inhibit the infection or replication of a virus.

Art Unit: 1632

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, recognized divergent subject matter, and that the search for one Group is not required for the search of another, restriction for examination purposes as indicated is proper.

This application contains claims directed to the following patentably distinct species of the claimed invention: claims 6, 9, 12, 13, 19, 24, 29, 32, 35, 40, 42 involve an ISG15-conjugate wherein the ISG15-conjugate is selected from ISG15-phospholipase C γ 1, ISG15-Jak1, ISG15 ERK1, ISG15-ERK2, ISG15-Stat1 and a variant thereof.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 1, 8, 11, 13, 19, 24, 29, 32, 35, 38, 41 are generic.

This application contains claims directed to the following patentably distinct species of the claimed invention: claims 2, 14, 23, 27, 37 involve further contact of cells with IFN α , IFN β , double-stranded ribonucleic acid or lipopolysaccharide.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, no claims are generic.

Art Unit: 1632

This application contains claims directed to the following patentably distinct species of the claimed invention: claim 31 is to a method of inhibiting the infection or replication of a virus, comprising virus selected from the group consisting of hepatitis B virus, hepatitis C virus, human immunodeficiency virus, Epstein-Barr virus, herpes virus, rhinovirus, picornavirus, lentivirus, cytomegalovirus, respiratory syncytial virus, and poxvirus.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claim 29 is generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the

Art Unit: 1632

inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Joanne Hama, Ph.D. whose telephone number is 571-272-2911. The examiner can normally be reached Monday through Thursday and alternate Fridays from 9:00-5:00.

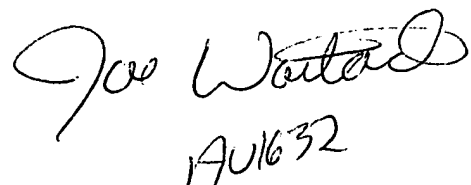
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson, Ph.D. can be reached on 571-272-0804. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Art Unit: 1632

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public. For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

JH



Joe Winters
AU1632